UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

IN RE NUVARING® PRODUCTS LIABILITY LITIGATION	)	Case No. 4:08-MD-1964 RWS
	)	ALL CASES

MEMORANDUM AND ORDER

Defendants in this matter (collectively, "Organon") bring a Daubert challenge against Plaintiffs' expert Suzanne Parisian, M.D. Organon asks me to find as a matter of law that Dr. Parisian is unqualified as an expert and that her opinions are so unreliable and unhelpful that they should be excluded from being tested by any cross-examination at trial, being weighed by any jury, or even limited in any respect by any trial judge. Plaintiffs oppose this motion by asserting Dr. Parisian's qualifications, reliability, and helpfulness to the jury. For reasons that follow, Defendants' motion will be denied.

I. BACKGROUND

This multi-district litigation (MDL) relates to the manufacture, marketing, and sale of the prescription pharmaceutical known as NuvaRing. NuvaRing, which is manufactured, marketed, and sold by Organon, is a member of a class of prescription drugs known as combined hormonal contraceptives, which contain an estrogen and a progestin component. Unlike oral CHCs, NuvaRing takes the form of a flexible ring which releases hormones over the course of treatment. The ring is vaginally inserted by women for birth control. Each month, the ring is removed and a new ring is inserted.

CHCs contain an estrogen, typically ethinyl estradiol ("EE"), and a progestin. The "generation" of CHC depends upon the type of progestin. Each "generation" of CHC typically

includes the following progestins: first-generation contains norethynodrel; second-generation contains levonorgestrel; and third-generation CHCs contain desogestrel, gestodene, or norgestimate. NuvaRing uses the active metabolite of desogestrel, etonogestrel, and is therefore considered a third-generation progestin.

Plaintiffs allege that the progestin used on the ring, etonogestrel, has been linked to an undisclosed increased risk of venous thromboembolism, including both deep vein thrombosis and pulmonary embolism.[1] Plaintiffs allege they have been injured by the use of NuvaRing and have asserted the following claims: strict products liability for defective manufacturing, defective design, failure to test, and inadequate warnings; breach of express / implied warranties; and negligence.

In support of these claims, Plaintiffs proffer Dr. Suzanne Parisian as an expert in FDA regulations and pharmaceutical labeling and promotions. Dr. Parisian is offered to testify about alleged shortcomings in Organon's compliance with FDA regulations.

From 1991 to 1993, Dr. Parisian worked for the FDA as a medical officer in the Office of Health Affairs (OHA), within the Center for Devices and Radiological Health (CDRH). From March 1993 to December 1993, Dr. Parisian served the FDA as a medical officer in the Office of Device Evaluation (ODE). In January 1994, Dr. Parisian became a chief medical officer in the ODE, where she remained until 1995.

Since 1995, Dr. Parisian has operated a consulting firm specializing in the FDA's regulation of devices and pharmaceuticals. Her consulting work has been for both consumer plaintiffs as well as manufacturers and has required that she stay up-to-date on the applicable

[1] Venous thromboembolism is a blood clot that forms within a vein. Deep vein thrombosis is a blood clot that forms in a vein not externally visible, typically in the veins of the lower extremities. A pulmonary embolism forms when part or all of a blood clot breaks free and lodges in one of the lungs. These conditions have varying severity and can be life threatening.

statutes and regulations. While consulting for a pharmaceutical company, she assisted in submitting an Investigational New Drug ("IND") application to the FDA. In 2001, Dr. Parisian authored and self-published a book, *FDA Inside & Out*, which reviewed and examined FDA processes, the history of FDA actions, requirements for each Center of the FDA, and FDCA requirements. The book is available in 71 libraries, including the FDA Biosciences Library and at the Center for Disease Control and Prevention.

Organon presents three arguments against the admission of Dr. Parisian as an expert: 1) Dr. Parisian is unqualified; 2) Dr. Parisian's methods are unreliable; and 3) Dr. Parisian's testimony will be unhelpful to the jury and uncontrollable at trial.

II. LEGAL STANDARD

Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), govern the admissibility of expert testimony. The Daubert standard applies to all expert testimony, whether based on scientific competence or other specialized or technical expertise. See Polski v. Quigley Corp., 538 F.3d 836, 838 (8th Cir. 2008). Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

"[I]t is the responsibility of the trial judge to determine whether a particular expert has sufficient specialized knowledge to assist jurors in deciding the specific issues in the case." Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc., 254 F.3d 706, 715 (8th Cir. 2001). "Once initial expert qualifications and usefulness to the jury are established, however, a district court must continue to perform its gatekeeping role by ensuring that the actual testimony

does not exceed the scope of the expert's expertise, which if not done can render expert testimony unreliable . . . ." Id.

"When faced with a proffer of expert scientific testimony, the trial court must make 'a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.'" Polski, 538 F.3d at 838 (quoting Daubert, 509 U.S. at 592–93). Thus, under Rule 702, the trial judge also acts as a gatekeeper by screening evidence for relevance and reliability. Daubert, 509 U.S. at 589.

Thus, the district court applies a three-part test when screening expert testimony under Rule 702:

> First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires.

Polski, 538 F.3d at 839 (quoting Lauzon v. Senco Prods., Inc., 270 F.3d 681, 686 (8th Cir. 2001)).

"Rule 702 reflects an attempt to liberalize the rules governing the admission of expert testimony. The rule clearly is one of admissibility rather than exclusion." Lauzon, 270 F.3d at 686 (internal quotations and citations omitted). "The exclusion of an expert's opinion is proper only if it is so fundamentally unsupported that it can offer no assistance to the jury." Wood v. Minn. Mining & Mfg. Co., 112 F.3d 306, 309 (8th Cir. 1997) (internal quotations and citation omitted).

When assessing the reliability of expert testimony, a trial court should consider several factors, including: "(1) whether the concept has been tested, (2) whether the concept has been

subject to peer review, (3) what the known rate of error is, and (4) whether the concept is generally accepted by the community." Miller v. Baker Implement Co., 439 F.3d 407, 412 (8th Cir. 2006) (citing Daubert, 509 U.S. at 593–95). There is no requirement that courts rely on each factor, as the gatekeeping inquiry is flexible and must be "tied to the facts" of the particular case. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 150 (1999) (quoting Daubert, 509 U.S. at 591).

"[T]he rejection of expert testimony is the exception rather than the rule." Robinson v. GEICO General Ins. Co., 447 F.3d 1096, 1100 (8th Cir. 2006) (citing Fed. R. Evid. 702 advisory comm. note). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. at 596.

III. ANALYSIS

A. Qualifications

Organon argues that Dr. Parisian lacks the necessary qualifications to testify as to the regulation of drugs. Organon obtained declarations from two of Dr. Parisian's superiors at the FDA, Drs. Burlington and Alpert, that call into question the experience gained by Dr. Parisian during her stint at the FDA. Organon also attacks Dr. Parisian's qualifications to opine on "issues related to contraception and blood clotting," because, Organon argues, Dr. Parisian lacks epidemiological and other scientific expertise.

I find that Dr. Parisian's knowledge, skill, experience, training, and education qualify her to offer testimony concerning FDA regulatory and labeling issues. Dr. Parisian's FDA and pharmaceutical consulting experience, as well as the knowledge gained through researching and authoring her book on FDA regulations, provide her with specialized knowledge that will assist

the jury in this case. These qualifications are further bolstered by the eighteen years Dr. Parisian has spent conducting reviews and analyses of FDA regulations in the context of providing expert testimony in drug litigation.

As to Organon's second argument, Dr. Parisian's work with the FDA involved designing an epidemiology study and the review of pharmacological data. Moreover, Organon's own declarant, Dr. Susan Alpert, attested that medical officers like Dr. Parisian were required to analyze and rely upon the specialized reports of experts in various scientific fields. I therefore find Dr. Parisian qualified within the field of epidemiology and to analyze conclusions of other scientific experts and rely upon them when forming her own opinions.

Dr. Parisian is qualified to testify as an expert. Organon may address the weight of Dr. Parisian's testimony during cross-examination.

B. Methodology

Organon alleges that Dr. Parisian's methodology is deficient for two reasons: first, that she fails to use objective and generally accepted standards and second, that she selectively reviews materials. I find that Dr. Parisian's methodology is reliable.

Organon argues that when reviewing a drug for approval, the FDA takes into consideration knowledge about similar products and class labeling and that Dr. Parisian failed to follow these procedures. However, Dr. Parisian stated that she reviewed the approval package for Mircette and Desogen, two oral combined hormonal contraceptives. (Doc. 1375, Exh. 8, Parisian Dep. 10/25/11 at 34:16–38:4). Dr. Parisian also testified that she compared the NuvaRing label to Estring, a vaginal sustained-release product used for hormone replacement therapy. Id. Dr. Parisian further stated that she considered class-labeling information. (Doc. 1485, Exh. 1, Parisian Decl. at ¶ 58). I find that Dr. Parisian followed the proper standards.

Organon's second argument fails to establish at this stage of the proceedings that Dr. Parisian's review was so deficient as to render her opinion *per se* unreliable. Organon argues that Dr. Parisian should have reviewed the entirety of the NDA package and that she "cherry picked" data. The record indicates that FDA reviewing officers rely upon the specialized reports and summaries of experts, rather than a first-hand review of the voluminous NDA package. Dr. Parisian applied the methodology gained from her experience with FDA regulation and reviewed the same materials that were reviewed by the FDA medical officers. As to cherry picking data, the Eighth Circuit has recently made clear that such allegations should be left for cross-examination. See Kuhn v. Wyeth, Inc., 686 F.3d 618, 633 (8th Cir. 2012). I therefore find that Dr. Parisian's methodology is sufficiently reliable for admission.

C. Usefulness to the Jury

Finally, Organon argues Dr. Parisian should be excluded from trial because her testimony will consist entirely of improper advocacy and speculation, will not assist the jury, and will be uncontrollable at trial. Dr. Parisian's report does provide a narrative summary of evidence that would be best presented to the jury directly. Dr. Parisian's report also addresses topics, including state of mind and intent, which can be decided by the jury without expert assistance. However, Dr. Parisian's report contains numerous other matters which will be helpful to the jury. As this Court is more than capable of restricting Dr. Parisian to appropriate subjects at trial through timely objections, I will not exclude her from testifying.

IV. CONCLUSION

For the foregoing reasons, I find Dr. Parisian qualified to opine as to the matters stated in her expert report. Further, these opinions, as grounded in credible articles, studies, reports, and

personal experience, are based on a reliable methodology. Finally, Dr. Parisian's report contains matters that shall be helpful to the finder of fact.

Accordingly,

IT IS HEREBY ORDERED that Defendants' motion to exclude Plaintiffs' expert Dr. Suzanne Parisian [Doc. 1299**]** is **DENIED.**

RODNEY W. SIPPEL
UNITED STATES DISTRICT JUDGE

Dated this 4th day of March, 2013.